



January 30, 2004

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 04-05

Marketing and
Regulatory
Programs

Animal and Plant
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Veterinary Services

Center for Veterinary
Biologics
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Subject: Replacement of the Center for Veterinary Biologics' IgG Species Standard for Qualification of IgG Reference Product for Failure of Passive Transfer Products

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics

This notice provides information on the availability of new Bovine and Equine IgG Species Standards used for qualifying bovine and equine IgG reference products which are used for release of serials for failure of passive transfer products in accordance with Title 9, Code of Federal Regulations, Part 113, Section 499 (9 CFR 113.499).

The Center for Veterinary Biologics (CVB) has developed concentrated Secondary Reference Sera which must be diluted in order to prepare the IgG Species Standard for bovine and equine IgG. These new references are traceable to well characterized primary references of IgG that are maintained by CVB. The Secondary Reference Sera will be provided upon request to United States veterinary biologics manufacturers for use in qualifying the firm's IgG Reference Product.

Reference and Reagent Sheets provided with the Secondary Reference Sera will have instructions for dilution and storage, as well as specification of the IgG concentration.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics



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